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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,467	12/04/2001	Keith D. Allen	R-758	7217

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/005,467	**Applicant(s)** ALLEN, KEITH D.	
	Examiner Celine X. Qian Ph.D.	**Art Unit** 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED _____ FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *22 June 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *28-32,37,47 and 52-58*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 3. NOTE: the proposed amendment presents new claims that would require further consideration. The newly presented claims 59-63 are drawn to a PTP36 knockout female mouse with newly presented phenotype, therefore, would require further consideration for the patentability. As such, the amendment will not be entered.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments are not persuasive to overcome the 101/1121st rejection of the record. In response to Applicant's response regarding any knockout mouse has a well-established utility, the examiner does not agree with Applicant's assertion that the claimed invention has a well-established utility. Applicant is reminded that in MPEP, the guideline for the utility requirement clearly states: "An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible." In the instant case, the utility that applies to any knockout mouse is not specific to the claimed invention, the CPN transgenic mouse having a null allele. It was well known to knock out a gene to determine its function or what will happen when the gene is not expressed. However, scientific "utility" is not the same as "patentable utility" or a "well-established" utility, of which must be specific, substantial and credible. At the time of filing, knockout mice were used for further research in the art as indicated by the quotations cited by Applicant, for example, studying gene function. However, further research does not rise to the level of a "well-established utility" because such a utility is not substantial. The utility guidelines specifically state that further research is not a "substantial utility." The MPEP states "the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities": A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved..." In this case, further study of mice would have been required to determine how to use the mouse of applicant's invention according to the embodiments described in the specification. Applicant's assertion that the claimed mouse is useful to study the association of CPN gene with the phenotype is an invitation for further research on the claimed invention in which the function of said invention Applicant clearly does not know. Further study would be required to characterize such association because the teaching of the specification is not sufficient to establish whether the phenotype is directly result from the gene disruption. Further study would also be required to determine the function of the disrupted gene. Furthermore, the overall phenotype of the claimed mice does not correlate to any disorder; therefore, further study would be required to determine how to use the mice to study a disorder, screening drugs and treatment for such disorder. Thus, using the mice claimed for further research is not a "substantial utility."
In response to Applicant's argument with regard to specific utility, Applicant is again reminded that the asserted utility of the claimed invention need to be credible, substantial and specific according to the 101 statue. The utility of studying PTP36 function using the claimed mouse fails to meet this requirement (see reasons given above). Moreover, if the phenotype of the mouse is not directly resulted from the disruption of the gene, the association between the phenotype is not specific to the PTP36 gene. As such, the claimed mouse fails to meet the standard.
In response to Applicant's argument regard using the transgenic mouse comprising null-reporter allele to study the gene expression, Applicant is reminded that studying the expression of a gene of which the function is not known is not a substantial utility. Studying the expression of a gene for the purpose of exploiting said gene function is not a substantial utility because further research is required to determine said gene function, and such gene expression pattern merely provides a clue for said gene function. The "clue" does not rise to the level of a substantial utility. Similarly, studying the expression of a gene for the purpose of determine how to use said transgenic mouse constitutes further research to determine how to use the claimed product, thus it does not provide a substantial utility to the claimed product. Therefore, the specification fails to teach a patentable utility for the claimed mouse.
In response to Applicant's argument of the commercial sale of the claimed mouse, Applicant is reminded that the sale of a product does not automatically gives the product patentable use according to the statue of 35 U.S.C.101 and the utility guideline set forth in the MPEP. Commercial success is only considered as secondary evidence for overcoming a 103 (a) rejection according to guidelines set by MPEP. Brenner v. Manson does not validate the notion that commercial use automatically gives a claimed product patentable utility. The purchase of the claimed mouse by a large pharmaceutical company neither proves commercial success of the claimed mouse nor does it gives the claimed mouse a patentable utility. The case law of Phillips Petroleum Co. v. U.S. Steel Corp. 6 USPQ 2d 1065 talks about commercial success in context as secondary consideration in favor of nonobviousness (see page 1096). It states "of course, there must be a nexus "between the merits of the claimed invention and the evidence offered if that evidence is to be given substantial weight enroute to conclusion on the obviousness issue." Stratoflex , 713 F.2d at 1539 [218 USPQ at 879] (noting Solder Removal Co. v. United States Intern. Trade , 582 F.2d 628, 637 [199 USPQ 129, 137] (C.C.P.A. 1978)). Crystalline polypropylene is one of the most widely used chemical compositions in commerce today. Worldwide demand is presently approximately fourteen billion pounds, with the United States' demand totaling nearly six billion pounds per year. (Mark, Tr. at 503.) 68 Experts from both sides were in general agreement that crystallinity is the characteristic which gives polypropylene its immense commercial value." According to the case law, the commercial success is established by the worldwide use of the claimed compositions and the generation of high revenue from the sale of the claimed composition. However, the sale of the present claimed invention to one pharmaceutical company clearly does not mount to such "commercial success." Applicant is reminded that subscription of a database is different from actually using the data obtained from the claimed invention, wherein the database presumably contains much more information other than that is related to the claimed invention. The case law of 9 USPQ 2d 1461 affirmed the earlier case but does not deal with commercial success and practical utility. It states: "correct finding of infringement of otherwise valid claims mandates as a matter of law a finding of utility under §101," however, it does not apply to the current situation since there is no infringement of the current claimed invention. Furthermore, it is unclear how the claimed invention is going to be used by this pharmaceutical company. For instance, if the company is using the mouse for studying the function of the CPN gene, it at most gives the claimed mouse a scientific utility, which is different from the patentable utility for reasons discussed above. With regard to the sentence quoted from Lipscomb's Walker on Patents, the examiner cannot comment on it because it is unclear what context such statement was made. For example, what evidence should Applicants provide to establish sales and commercial demand? Is it a secondary evidence to some other requirement? A search of the book reveals that it ends at page 530, there is no page or paragraph 562. As such, this statement alone does not support that sale of this mouse to one company automatically gives the claimed mouse a patentable utility. Therefore, based on the utility requirement set forth in MPEP, the sale of the mouse to one company does not give the claimed mouse a patentable utility.
In response to Applicant's argument regard In re Brana, the examiner does not agree that this case law applies to the instant

case. In the Brana decision, the court concluded that the mouse tumor models (leukemia cell lines were originally derived from lymphocytic leukemia in mice) represent a specific disease against which the claimed compounds were alleged to be effective. As such, the claimed compound has credible, substantial and specific utility. In Brana, the asserted utility meets the requirement of the statue because the claimed compounds are effective in a valid and specific mouse tumor model. However, in the instance case, the claimed knockout mouse does not have a credible, substantial and specific use because the specification does not teach what specific disease model the claimed mouse represents and/or what type of drug the claimed mouse can screen. The mere statement that the claimed mouse can be used to study depression and/or pain is not sufficient to establish a credible, substantial and specific utility for the claimed mouse. The prior art is silent on the claimed mouse thus does not recognize any well-established utility for the claimed mouse. Moreover, the utility of using the claimed mouse to study CPN function or association to the phenotype is not a credible, substantial and specific utility for reasons discussed above. Therefore, unlike Brana, the instant specification fails to provide a credible, substantial and specific utility for the claimed mouse.
For reasons given in the previous office action and above, the specification fails to disclose a credible, substantial and specific use for the claimed mouse and one skilled in the art would not know how to use the claimed mouse according to the embodiments disclosed by the instant specification.

Newly added claims 59-63 would require further consideration and will not be entered for reason given above.

CELIAN QIAN
PATENT EXAMINER